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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,490	03/19/2001	Majid Mehtali	032751-061	9942

7590 01/04/2007

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EXAMINER	
GUZO, DAVID	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/810,490	MEHTALI ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-46 and 48-64* is/are pending in the application.

4a) Of the above claim(s) *60 and 61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-46,48-59 and 62-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Claims 60-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/2/04.

Applicants, in the amendment submitted on 3/19/01 with the transmittal letter claimed benefit of the parent application 08/809,562, filed 3/31/97. No other claim for priority was made in said amendment. If applicants seek to claim benefit for the PCT/FR96/01165 application (and hence provide continuity back to the French 95 08946 and 96 04413 applications), applicants must amend the first page of the specification (or supply a Application Data Sheet) to claim benefit for this PCT application.

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/FR96/01165, filed 7/24/96. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application

must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Upon further review, the examiner notes that applicants did claim priority for the PCT in the Transmittal papers. However, applicants are still required to submit the reference to the PCT application in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. No petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required.

The Abstract submitted 3/23/05 is acceptable.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 54-57 and 64 stand rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al. (US 5,856,152) or Wilson et al. (US 5,585,362).

This rejection is maintained for reasons of record in the previous Office Action (mailed 6/16/04) and for reasons outlined below. The rejection is expanded to include new claim 64 as a result of applicants' amendment filed 9/1/05. In new Claim 64 applicants claim a composition comprising a complementation cell which complements a viral vector function, comprising an inducer and/or a repressor, in combination with a suitable carrier.

Applicants traverse this rejection by asserting that the claims, as amended, are directed to a viral vector retaining an expression unit containing one or more viral genes wherein the regulatory elements controlling expression of the viral genes comprise one or more heterologous regulator sequences. Applicants assert that neither Wilson et al. reference (the '152 and '362 patents) teaches inclusion of heterologous regulator sequences in the viral expression unit and thus fail to anticipate the claimed invention.

Applicant's arguments filed 9/1/05 have been fully considered but they are not persuasive. It is noted that Claims 54-57 **do not contain** the limitations that applicants have introduced, by amendment, into independent claim 39 and, hence, said arguments are not persuasive. With regard to new Claim 64, both Wilson et al. references teach compositions comprising complementing cells (i.e. 293 cells) which are capable of complementing a viral function, said cells comprising an inducer (i.e. E1a) in

combination with a suitable carrier (i.e. tissue culture media). The rejection is therefore maintained.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54-57 and 64 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 23-29, 31-34 and 36-41 of U.S. Patent No. 6,204,060 (hereafter the '060 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons of record in the previous Office Action.

Applicants traverse this rejection by asserting that the claims, as amended, are now drawn to viral vectors (i.e. viral vectors derived from herpesviruses,

cytomegaloviruses, AAV and poxviruses) distinct from the adenoviral vectors claimed in the '060 patent.

Applicant's arguments have been fully considered but they are not persuasive. Instant claims 54-57 and 64 are not limited to viral vectors derived from herpesviruses, cytomegaloviruses, AAV and poxviruses or to complementation cells which complement herpesviral, cytomegaloviral, AAV and poxviral vectors. As applicants' arguments are not germane to Claims 54-57 and 64, the double patenting rejection against claims 54-57 and 64 is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-46, 48-64 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below. The rejection is expanded to include new claims 62-64 as a result of applicants' amendment filed 9/1/05.

Applicants traverse this rejection by amending the claims to recite viral vectors derived from herpesviruses, CMV, AAV and poxviruses and asserting that said viral

vectors are well known in the art and have been previously manipulated so as to express genes of interest and generate infectious particles.

Applicants' arguments have been carefully considered but are not persuasive. Applicants have provided no written description of any aspects of the claimed invention with viruses other than adenoviruses. No species of the claimed invention, other than those involving adenoviruses, have been described and hence no representative examples of the claimed invention using herpesviruses, CMV, AAV and poxviruses have been disclosed. Herpesviruses, CMV, AAV and poxviruses are unrelated to adenoviruses and the teachings of the instant specification with regard to the generation of adenoviral complementing cell lines, adenoviral vectors, etc. cannot be extrapolated to unrelated viruses such as herpesviruses, CMV, AAV and poxviruses. Essentially, applicants are asserting that the skilled artisan could disregard the instant specification (as it provides no disclosure on generating the claimed viral vectors and complementing cell lines derived from herpesviruses, CMV, AAV and poxviruses) and rely entirely upon the prior art to provide the essential teachings sufficient to practice the claimed invention. Clearly, the instant specification does not provide a disclosure sufficient to show that the invention, using the recited viruses, was complete and ready for patenting (See MPEP 2163.02):

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or

she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs.,Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

It must be considered that the skilled artisan would not conclude that applicants were in possession of the claimed invention. The rejection is therefore maintained.

Claims 39-46, 48-53, 58-59 and 62-63 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is necessitated by applicants' amendment filed 9/1/05. The basis of the rejection however, is the same as recited in the previous 35 USC 112, 1st paragraph, scope of enablement, rejection (see Office Action mailed 6/16/04). Said scope of enablement rejection was predicated upon the lack of enablement for practicing the invention with viruses other than adenoviruses.

Applicants traverse this rejection (as it applies to the previous scope of enablement rejection) by amending the claims to recite viral vectors and complementing cell lines based upon herpesviruses, CMV, AAV and poxviruses and arguing that as of March 1997, the skilled artisan could practice the claimed invention without undue experimentation. Applicants assert that the skilled artisan could use general, known in the art, techniques of genetic engineering to generate the specific viral vectors and complementing cells recited in the claims.

Applicants' arguments have been carefully considered but are not persuasive. As noted in the previous Office Action, applicants provide no disclosure of starting materials, cell lines, culture conditions and methods for preparing viral vectors and complementing cell lines with the recited characteristics. The specification indicates that the skilled artisan, using prior art teachings, could reduce to practice the claimed invention with the recited viruses. However, the specification cannot merely rely on what was known in the art to provide an enabling disclosure of a claimed invention. As noted in *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001 (CAFC 1997):

> Rule that specification need not disclose what is well known in art means only that omission of minor details does not cause specification to fail to meet enablement requirement, and is not substitute for basic enabling disclosure; if there is no disclosure of any starting material or of any conditions under which claimed process can be carried

out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art.

Since it is not disputed that the specification, as filed, does not provide starting materials or conditions under which the claimed herpesviral, CMV, AAV and poxviral vector compositions and complementing cells can be made, it is concluded that undue experimentation is required.

Claims 54-57 and 64 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for complementation cells which complement adenoviral functions comprising an inducer and/or repressors, does not reasonably provide enablement for complementation cells which complement any viral functions comprising an inducer and/or repressors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined above in the 35 USC 112, 1st paragraph rejection of claims 39-46, 48-53, 58-59 and 62-63. Applicants' arguments pertaining to the enablement rejection of record have been addressed in the above rejection and will not be repeated again here.

The drawings filed 12/20/04 have been entered and are acceptable.

Any rejections not repeated in this Office Action are withdrawn.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
December 14, 2006

DAVID GUZO
PRIMARY EXAMINER